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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
04/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,415	MACPHEE ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1-21-09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *16-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-5-07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response to election requirement dated 1-21-09 is acknowledged.

Claims 1-24 are pending.

1. ***Upon reconsideration, the election requirement of the previous action has been withdrawn and all the claims 1-24 have been examined.***

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-3, 11-16, 19 and 22 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,762,336. Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims recite a hemostatic dressing comprising a first fibrinogen layer, thrombin layer adjacent to said first fibrinogen layer;

and a second fibrinogen layer adjacent to said thrombin layer, wherein the thrombin layer is noncoextensive with the first fibrinogen layer and/or second fibrinogen layer.

4. Patented claims also recite a hemostatic dressing with thrombin sandwiched between the two fibrinogen layers and only differ from the instant claims in that the patented claims do not state that the thrombin is noncoextensive with first and/or second layer.

5. However, instant specification on page 4-5 describes as follows: "thrombin layer that is said to be "noncoextensive" with a fibrinogen layer is one in which the spatial boundaries of the thrombin layer in two dimensions are smaller than the spatial boundaries of one or both fibrinogen layers such that the thrombin layer is coextensive with only about 5% to about 95% of the surface area of the first fibrinogen layer of the hemostatic dressing and/or coextensive with only about 5% to about 95% of the surface layer of the second fibrinogen layer of the hemostatic dressing, independently. For example, the thrombin layer can be coextensive with about 10, 20, 30, 40, 50, 60, 70, 75, 80, or 90 % of the surface area of each of the first and second fibrinogen layers, 30 independently. A thrombin layer that is "coextensive" with a fibrinogen layer provides full coverage of the fibrinogen layer and is coextensive with 100% of the surface area of the fibrinogen layer. A thrombin layer can be noncoextensive with the first fibrinogen layer and yet be coextensive with the second fibrinogen layer, or vice versa, e.g., by employing fibrinogen layers having different total 5 surface areas or shapes." Thus, the word "about" provides a latitude for 95% coextensive such that the thrombin layer is coextensive with the first and/or second fibrinogen layer. Therefore, the instant

sandwich arrangement of fibrinogen-thrombin-fibrinogen layer is anticipated by the patented claims. The patented claims also recite a resorbable material, a polymer, and a method of preparing the dressing and a method of applying the bandage similar to the instant claims and therefore the instant claims are anticipated by patented claims.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-3, 11-16, 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/59647 (WO).

WO teaches a haemostatic multilayer bandage that comprises a thrombin layer between two fibrinogen layers, other resorbable materials such as glycolic acid or lactic acid based polymers or copolymers and haemostatic sandwich bandage is useful for the treatment of wounded tissue (abstract and pages 3-4). WO also teaches the instant claimed backing layer, fillers, solubilizing agents, foaming agents (pages 7 and 9). WO teaches the same method of applying the bandage

for wound healing on page 11, L 1-10. While WO fails to teach the claimed limitation of non-coextensive thrombin layer with the first or second fibrinogen layer, given the scope of the term "noncoextensive" described above, the sandwich bandage described by WO anticipates the instant bandage system.

8. Claims 1-3, 11-16, 19 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,762,336 to MacPhee et al ('336).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

9. US '336 also describes a haemostatic multilayer bandage that comprises a thrombin layer between two fibrinogen layers, other resorbable materials such as glycolic acid or lactic acid based polymers or copolymers and haemostatic sandwich bandage is useful for the treatment of wounded tissue (abstract, col. 2, L 21-65). '336 also teach the instant claimed backing layer, fillers, solubilizing agents, foaming agents (col. 2, L 66-col. 3, L 1-13). '336 teach the same method of applying the bandage for wound healing on page 11, L 1-10. While '336 fails to teach the claimed limitation of non-coextensive thrombin layer with the first or second fibrinogen layer, given the scope of the term "noncoextensive" described above, the sandwich bandage described by '336 anticipates the instant bandage system.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 4-7, 20 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US 6,762,336 to MacPhee et al ('336) or WO 99/59647 (WO), and further in view of US 2006/0179793 to Yewdall et al (Yewdall).

13. WO and US '336 discussed above fail to describe the claimed percentage range of noncoextensive thrombin in the sandwiched hemostatic dressing. It is noted that US '336 claims priority to WO 99/59647 (WO) and both documents have the same disclosure.

14. Yewdall teaches an improvement over the bandage of WO and teaches that bandage (prepared by WO) is further sealed and stored for conditions that prevent it from being brittle, ability to use at room temperature etc [0007]. Yewdall teaches using a container for mould in which the hemostatic bandage is present. According to figure 1 of Yewdall, the bandage comprises a lower absorbable bandage material, followed by a fibrinogen, thrombin, fibrinogen layers, where the top fibrinogen material is at the side of the bandage such that it covers the wound [0044]. Yewdall also states that the mould is not restricted to a specific sandwich structure. Thus, even though Yewdall does not explicitly state the "noncoextensive' feature of the instant claims, the arrangement described above by Yewdall reads on the same. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ a sandwich wound dressing such as that of US 336 or WO wherein at least the top fibrinogen layer extends over the sides of the sandwich because Yewdall teaches that the fibrinogen on the sides of the bandage adheres to the skin when applied. While the references fail to specifically teach the claimed percentages of 5%-95% or 20% - 50%, preparing sandwich hemostatic dressings with appropriate amounts of thrombin so as to achieve the formation of fibrin at the site of application so as to heal the help clot formation and thus wound healing would have been within the scope of a skilled artisan.

15. Claims 8-10 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US 6,762,336 to MacPhee et al ('336) or WO 99/59647 (WO),

as applied to claims 1-3, 11-16, 19 and 22 above, and further in view of US 6117425 to MacPhee et al ('425).

WO and US '336 fails to teach the application of and the application of thrombin as dots, spots or lines (claims 8-10) and also lacks hydrating the dressing as in claims 17-18.

US 425 teaches tissue sealant production where the ready to use bandage has a backing layer and dry powder materials comprising effective amount of thrombin and fibrinogen (col. 9, L 57-66) and the outer adhesive material is attached to the skin such that it directly forms a fibrin clot over the wound (lines bridging col. 29-30). '425 further teach an additional hydrating layer in addition to the layer of dry powdered thrombin and fibrinogen layer. US 425 teach that the adhesive is hydrated sufficiently for the dressing to be sticky and also forms a seal on the wounded tissue directly. Thus it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to employ thrombin as a dry powdered material, which appears as spots, dots or other patterns of choice and also hydrate the dressing with external or internal hydration source because '425 teaches formation of a sealant on the wound directly due to the hydration of the dry powdered materials thus rendering the dressing sticky.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
March 29, 2009